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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/495,186	02/01/00	MCMICHAEL J	13024/35946

HM12/1018
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EXAMINER	
WILSON,M	
ART UNIT	**PAPER NUMBER**
1633	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/495,186	Applicant(s) McMichael et al.
	Examiner Wilson, Michael C.	Group Art Unit 1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5, 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Claims 1-20 are pending and under consideration in the instant application.

The Declaration for Patent Application filed 5-4-00, paper number 6, has been entered.

The Information Disclosure Statement filed 2-25-00, paper number 5, has been considered and made of record.

Specification

1. The disclosure is objected to because of the following informalities: "injected" on page 14, line 15. It is unclear what applicants consider an "injected" tympanic membrane. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating respiratory congestion in an allergy patient comprising: sublingually administering in a manner so as not to effect gene transfer an effective amount of DNA in a pharmaceutically-acceptable vehicle to an allergy patient having respiratory

congestion wherein said method results in reduction of respiratory congestion, does not reasonably provide enablement for treating any allergy symptom using any route of delivery. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-7 are directed toward a method of treating allergy symptoms; however, the claims do not recite a step wherein a therapeutic effect is obtained. The purpose of administering DNA to allergy patients is to treat allergy symptoms (page 3, line 28). For the claims to be of a disclosed use and to reflect the preamble of claim 1, the claims should recite a step wherein a therapeutic effect is obtained.

Claims 1-7 encompass obtaining any therapeutic effect and treating any symptom of allergies. The state of the art at the time of filing was that allergies include immune reactions against bee stings, bug bites, snake bites, pollen, dust, foods, inhalants, chemicals et al. Symptoms of allergies include congestion, swelling, irritation, difficulty breathing, vasoconstriction and anaphylactic shock.

The specification teaches administering DNA to a patient with broad spectrum allergies to foods and inhalants and obtaining the patients "preexposure state" (page 17, lines 22-29). The specification does not teach the patients "preexposure state" so as to determine which symptoms were alleviated. It is unclear whether "preexposure" refers to prior to administration or to prior to exposure to an allergen. While the symptoms of the patient after exposure to "high humidity

and 'heavy' air" are described, it is unclear that the patient was exposed to "high humidity" or "heavy air" prior to DNA administration. It is unclear which allergen the patient was exposed to prior to administering DNA, which symptoms the patient had prior to administration of DNA and which symptoms were alleviated.

Example XXXI teaches describes a patient with "sensitivity to grasses and hay leading to congestion, headache, irritated eyes and lethargy." The specification predicts that DNA administration prior to exposure or shortly thereafter results in "complete relief." The specification does not teach obtaining any therapeutic effect in the patient, teach what symptoms are considered "complete relief" or whether the "exposure" was to grasses or hay which may cause different immune responses. Likewise, Examples XXXII and XXXIII are prophetic and do not teach the symptoms prior to DNA administration or the symptoms that are ameliorated after DNA administration. Overall, applicants have not provided a correlation between delivery of DNA to treating symptoms of allergies as claimed.

Examples I-X teach decreasing respiratory congestion in patients caused by various conditions such as COPD, rhinitis and sinusitis. Congestion as disclosed in examples I-X correlate with congestion in allergy patients because both include thick mucous, nasal congestion and sinus congestion. Therefore, one of skill would have been able to determine the parameters required to treat respiratory congestion in an allergy patient using DNA. The specification does not correlate treating congestion to treating swelling, irritation, difficulty breathing, vasoconstriction or anaphylactic shock caused by any allergy. It would require one of skill undue

experimentation to treat swelling, irritation, difficulty breathing, vasoconstriction or anaphylactic shock caused by any allergy using DNA delivered by any route of delivery as broadly encompassed by the claims.

Claims 1 and 3-6 encompass using any route of DNA delivery and claim 7 recites the limitation of administering the DNA sublingually, subcutaneously, intravenously, intramuscularly or intrathecally. Examples I-X require sublingual administration to relieve congestion. Examples XXX-XXXI require sublingual administration but do not enable treating allergies for reasons cited above. Examples XXXII and XXXIII do not teach the route of administration and do not enable treating allergies for reasons cited above. The specification does not correlate the administration of DNA sublingually to administration of DNA subcutaneously, intravenously, intramuscularly, intrathecally or any other route of delivery such that therapeutic results could be obtained. It would require one of skill undue experimentation to determine the parameters required to deliver DNA subcutaneously, intravenously, intramuscularly, intrathecally or using any other route of delivery such that therapeutic results could be obtained. Therefore, the specification only enables treating respiratory congestion in an allergy patient using DNA administered sublingually.

In view of the lack of guidance in the specification regarding how to treat any symptom of allergies caused by any allergen using any route of administration, the lack of correlation between congestion and other symptoms of allergies, the state of the art, the examples provided and the

breadth of the claims, the ordinary artisan at the time of the instant invention would not have known how to make and/or use the claimed invention with a reasonable expectation of success.

3. Claims 8-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating respiratory congestion in a patient with asthma comprising: sublingually administering in a manner so as not to effect gene transfer and expression a therapeutically effective amount of DNA in a pharmaceutically-acceptable vehicle to an asthma patient with respiratory congestion, wherein said method results in a reduction in respiratory congestion, does not reasonably provide enablement for treating any symptom of asthma or using any route of delivery. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 8-14 are directed toward a method of treating asthma symptoms; however, the claims do not recite a step wherein a therapeutic effect is obtained. The purpose of administering DNA to asthma patients is to treat asthma symptoms (page 4, line 3). For the claims to be of a disclosed use and to reflect the preamble of claim 8, the claims should recite a step wherein a therapeutic effect is obtained.

Claims 8-14 encompass obtaining any therapeutic effect and treating any symptom of asthma. The state of the art at the time of filing was that asthma symptoms include an increase in mucous production, plugs of mucous in the airways, wheezing, shortness of breath and constriction of the airways (1988, The Textbook of Respiratory Medicine, John F. Murray, ed.,

W.B. Saunders Company, Philadelphia; see page 1038, column 2, line 27-31). The specification teaches administering DNA to an asthma patient with restricted physical activity resulted in the patient becoming able to run several miles daily and wok without undue fatigue (page 19, lines 8-12). DNA administered to an asthma patient also resulted in improved respiratory function (page 19, lines 15-19). In addition, Examples I-X teach decreasing respiratory congestion in patients caused by various conditions such as COPD, rhinitis and sinusitis. Respiratory congestion as disclosed in examples I-X correlate with respiratory congestion in asthma patients such as overproduction of mucous, thick mucous, nasal congestion and sinus congestion. Therefore, one of skill would have been able to determine the parameters required to treat respiratory congestion, such as overproduction of mucous, thick mucous, nasal congestion or sinus congestion, in an asthma patient using DNA. The specification does not correlate treating respiratory congestion to treating constriction of airways or asthma symptoms that are not associated with overproduction of mucous. It would require one of skill undue experimentation to treat constriction of airways or asthma symptoms that are not associated with overproduction of mucous using DNA delivered by any route of delivery as broadly encompassed by the claims because the invention relates to degrading DNA in sputum to increase the ability of the patient to evacuate sputum from the airways (page 5, line 19). Therefore, the claims should be limited to treating respiratory congestion in asthma patients.

Claims 8 and 10-13 encompass using any route of DNA delivery and claim 14 recites the limitation of administering the DNA sublingually, subcutaneously, intravenously, intramuscularly

or intrathecally. Examples I-X require sublingual administration to relieve congestion. Examples XXXIV-XXXV require sublingual administration. The specification does not correlate the administration of DNA sublingually to administration of DNA subcutaneously, intravenously, intramuscularly, intrathecally such that therapeutic results could be obtained. It would require one of skill undue experimentation to determine the parameters required to deliver DNA subcutaneously, intravenously, intramuscularly, intrathecally such that therapeutic results could be obtained. Therefore, the specification only enables treating respiratory congestion in an asthma patient using DNA administered sublingually.

In view of the lack of guidance in the specification regarding how to treat any symptom of asthma using any route of administration, the lack of correlation between respiratory congestion and symptoms of asthma such as constriction of airways and symptoms not associated with increased mucous, the state of the art, the examples provided and the breadth of the claims, the ordinary artisan at the time of the instant invention would not have known how to make and/or use the claimed invention with a reasonable expectation of success.

4. Claims 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating symptoms otitis media comprising the step of: sublingually administering in a manner so as not to effect gene transfer an effective amount of DNA in a pharmaceutically-acceptable vehicle to a patient having otitis media wherein said method results in improvement of one or more symptoms selected from the group consisting of fever, pain and fluid retention associated with otitis media **or** administering to the ear of a patient

having otitis media in a manner so as not to effect gene transfer an effective amount of eardrops to the ear, wherein said eardrops comprise DNA in a pharmaceutically-acceptable vehicle and wherein said method results in amelioration of pain associated with otitis media, does not reasonably provide enablement for treating any symptom of otitis media using any mode of topical administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 15-20 are directed toward a method of treating symptoms of otitis media; however, the claims do not recite a step wherein a therapeutic effect is obtained. The purpose of the specification is to treat symptoms of otitis media (page 3, lines 15-24). For the claims to be of a disclosed use and to reflect the preamble of claim 15, the claims should recite a step wherein a therapeutic effect is obtained.

The state of the art at the time of filing was such that a number of definitions of otitis media existed as discussed by Karver (September 1998, Ear, Nose and Throat disorders, Vol. 25, No. 3, pages 619-632). These include acute otitis media, otitis media with effusion, chronic otitis with perforation and chronic otitis media without perforation and are defined by Karver on page 619, 9 lines from the bottom through page 620. Otitis media is caused by *Streptococcus pneumoniae*, non-typeable *Haemophilus influenzae* and other bacteria and viruses (Klein, 1994, Clin. Infectious Diseases, Vol. 19, pages 823-833; page 824, column 2, "Microbiology"; see also page 1, line 20 of the instant specification).

Otitis media is associated with a number of symptoms (Baker, Nov. 1991, Pediatric Annals, Vol. 20, No. 11, pages 591-3, 596-598; page 591, column 2, line 6; Karver et al., see entire article) including pain, hearing loss, fever, nausea, vomiting, diarrhea, effusion in the middle ear (page 1, line 25 and page 2, line 3 of the instant application), irritability, headache, lethargy, anorexia, tinnitus, vertigo and nystagmus (Klein, page 826, paragraph bridging columns 1 and 2). The tympanic membrane may be retracted or bulging, red and immobile (Klein, page 826, column 2, line 9). Analgesics and decongestants are treatments for symptoms of fever, headache and congestion associated with otitis media; however, analgesics and decongestants are of no value in altering the course of or curing otitis media because they do not eliminate the number of organisms causing otitis media (Rosenfeld et al. 1996, Primary care, clinics in office practice, Vol. 23, pages 677-685; see page 683, 5th paragraph; Klein, page 829, column 1 , 4 lines from the bottom). The preferred method of treating otitis media is by eliminating the bacteria or virus using such compounds as antibiotics (Klein, column 2, "Management of acute otitis media"). Therefore, compounds used to treat symptoms of otitis media do not effect all symptoms unless they decrease the number of organisms infecting the host.

In addition, it was known at the time of filing that a placebo effect occurs in patients with otitis media receiving treatment. A placebo effect is an effect of medication that has no proven value-giving beneficial result (http://aspin.asu.edu/msnews/glossary.htm). Patients with otitis media caused *H. influenzae* by receiving placebo had about 48% of the *H. influenzae* killed, while patients with otitis media caused by pneumococcus had about 16% of the pneumococcus killed.

Both sets of patients experienced a decrease in symptoms associated with otitis media (Dagan et al. June 1998, Ear, Nose and Throat Journal, Vol. 77, pages 16-19; see page 1, paragraph bridging columns 1 and 2). Thus, a placebo effect occurs in patients receiving treatment for otitis media.

Claims 15-20 encompass treating any symptom of otitis media. However, the specification discloses treating pain (Examples XX, XXI, XXIV and XXV), temperature (Example XX), well being (Examples XX and XXII), redness (Example XXI) and effusion (which is considered to be equivalent to removal of fluid) (Examples XXI, XXIII and XXVII). The specification does not teach reducing the number of organisms causing otitis media. The specification does not teach ameliorating hearing loss, nausea, vomiting, diarrhea, irritability, headache, lethargy, anorexia, tinnitus, vertigo, nystagmus or a bulging, red, immobile tympanic membrane associated with otitis media. In addition, the specification does not compare the patients receiving treatment with patients receiving placebo such that one of skill could determine whether the DNA was responsible for the amelioration of symptoms or whether a placebo effect occurred. Given the unpredictability in the art regarding how to treat otitis media and the ability to treat any symptom of otitis media taken with the teachings in the specification, applicants invention could only be used to ameliorate pain, fever or fluid retention associated with otitis media. It would require one of skill undue experimentation to determine the parameters required to reduce the number of organisms causing otitis media or to treat any symptom of otitis media as broadly claimed.

Claim 15-19 encompass any method of topically administering DNA. Claim 20 recites the limitation of delivering the DNA in the form of eardrops. The specification states topical administration to the ear includes drops, creams, ointments or like (page 4, line 22). In the case of creams, ointments or other methods of administering, it is unclear where within the ear to deliver such compositions, i.e. an area of irritation or the entire ear. It is unclear whether applicants definition encompasses subcutaneous administration of DNA. Claim 15, however, does not require topical administration to the ear. It is unclear whether the claim encompasses sublingual administration because drops under the tongue may be considered topical (see 112/2nd). The specification teaches topical administration of drops of DNA to the ear canal and obtaining amelioration of pain (Example XXVIII; page 17, lines 5-8). The specification does not teach topical delivery by any method other than by ear drops such that a therapeutic effect could be obtained. The specification does not correlate the administration of ear drops to creams, ointments or subcutaneous administration such that equivalent results could be obtained. Given the unpredictability in the art regarding how to obtain a therapeutic effect of interest against otitis media, taken with the teachings in the specification , it would require one of skill undue experimentation to determine the parameters required to use any topical administration to treat any symptom of otitis media as broadly claimed. Therefore, the claims should be limited to administering eardrops of DNA to the ear such that pain is ameliorated.

The specification teaches a patient with respiratory infection and otitis media was treated with sublingual and topical administration of DNA and obtaining improved ears (Example

XXVIX, page 17, lines 11-15). It cannot be determined whether drops had any therapeutic effect in Example XXVIX because the DNA was also administered sublingually. It cannot be determined what therapeutic effect because applicants only state that the ears improved and do not teach what symptoms were ameliorated. Without such guidance, it is unclear how the example correlates to the claimed invention.

The specification teaches sublingual administration to patient with otitis media (page 14, line 11; page 15, line 4, line 17 and line 24; page 16, line 3, line 10, line 18, line 24). However, it is unclear how sublingual administration correlates to topical administration (see 112/2nd). Therefore, it unclear how the examples teaching sublingual administration correlate to the claims.

Therefore in view of the quantity of experimentation necessary to determine the parameters required to treat any symptom of otitis media, how to use any method of Topical administration to obtain any therapeutic effect, the state of the art at the time of filing, the breath of the claims, and the lack of correlation between the delivering DNA to the ear using eardrops and reducing pain and delivering DNA "topically" to treat any symptom of otitis media, the ordinary artisan at the time of the instant invention would not have known how to make and/or use the claimed invention with a reasonable expectation of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites the limitation of topically administering DNA and does not require delivery to the ear. The specification states topical administration includes drops, creams, ointments or like to the ear (page 4, line 22). However, the specification does not limit "topical administration" to the ear or to drops, creams or ointments. Nor does the specification teach what applicants consider "the like". It is unclear whether topical administration as claimed encompasses sublingual or subcutaneous administration. Sublingual administration is to the surface of the tissue under the tongue which may be considered topical. Subcutaneous administration to the ear may also be considered topical because it is delivered to the skin surface. Claim 20 is limited to eardrops; however, the claims are not limited to administering the drops to the ear. Since the eardrops may be the same composition as that used for sublingual administration, it is unclear whether the claim is limited to administered to the ear or whether the eardrops can be administered elsewhere such as under the tongue. Thus, the metes and bounds of the claims cannot be determined.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: obtaining a therapeutic effect.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by McMichael (US Patent 5,948,768, 9-7-00).

McMichael teaches administering liquid drops of 0.0006 mg of DNA sublingually to patients with congestion such as patients with otitis media or allergies (column 1, line 48; column 2, lines 1-26). Thus, McMichael anticipates all the limitations of the claims.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

7. Claims 8-14 are rejected under 35 U.S.C. 102(e) as being anticipated by McMichael (U.S. Patent 6,100,244, 8-8-00), McMichael (U.S. Patent 5,955,442, 9-21-99), McMichael (U.S.

Patent 5,726,160, 3-10-98), McMichael (US Patent 6,096,721, 8-1-00) or McMichael (US Patent 5,948,768, 9-7-1999).

McMichael teaches treating respiratory congestion by administering liquid drops of 0.0006 mg of DNA sublingually to asthma patients ('244, column 2 lines 1-37; column 6, line 61; '721, column 2, lines 1-37; column 6, line 54; '442, column 4, line 4; '768, column 2, lines 1-26; column 4, line 24; column 6, line 40; '160, column 4, line 3). Thus, McMichael anticipates all the limitation of the claims.

The applied references have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, they constitute prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the references was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

8. Claims 15-20 are rejected under 35 U.S.C. 102(e) as being anticipated by McMichael et al. (U.S. Patent 5,948,768, 9-7-99).

McMichael et al. teach delivering a liquid drop of 0.0006 mg DNA in water, saline, albumin or dextrose topically or sublingually to patients with otitis media (column 2, lines 1-24; see especially line 20). The instant claims recite "topically administering" DNA. However, because the phrase "topically administering" encompasses sublingual administration, either eardrops to the ear or sublingual administration as taught by McMichael anticipates "topically

administering" as claimed (see 112/2nd rejection). Therefore, McMichael anticipates all the limitation of the claims.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMichael (U.S. Patent 6,100,244, 8-8-00), McMichael (U.S. Patent 5,955,442, 9-21-99), McMichael (U.S. Patent 5,726,160, 3-10-98) or McMichael (US Patent 6,096,721, 8-1-00) in view of Kuby (1992, Immunology, Kuby, ed., W.H. Freeman and Company, page 360).

McMichael teaches treating respiratory congestion by administering liquid drops of 0.0006 mg of DNA sublingually to asthma patients ('244, column 2 lines 1-37; column 6, line 61; '721,

column 2, lines 1-37; column 6, line 54; '442, column 4, line 4; '160, column 4, line 3). McMichael does not specifically teach administering the DNA to a patient with allergy symptoms.

However, it would have been obvious to use the method of treating respiratory congestion as taught by McMichael to treat allergy symptoms because allergy patients also have respiratory congestion (Kuby, page 360, column 2, first full paragraph). One of ordinary skill in the art at the time the invention was made would have been motivated to use the method of McMichael in allergy patients to relieve congestion. Therefore, the combined teachings of McMichael and Kuby obviate claims 1-7.

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

10. Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMichael (U.S. Patent 6,100,244, 8-8-00), McMichael (U.S. Patent 5,955,442, 9-21-99), McMichael (U.S. Patent 5,726,160, 3-10-98) or McMichael (US Patent 6,096,721, 8-1-00) in view of O'Shea (May 1980, Annals or Otology, Rhinology, and Laryngology, Supp., Vol. 89, pages 285-289).

McMichael teaches treating respiratory congestion by administering liquid drops of 0.0006 mg of DNA sublingually to asthma patients ('244, column 2 lines 1-37; column 6, line 61; '721, column 2, lines 1-37; column 6, line 54; '442, column 4, line 4; '160, column 4, line 3). McMichael does not specifically teach delivering the DNA to patients with otitis media.

However, it would have been obvious to use the method of treating respiratory congestion as taught by McMichael to treat congestion in patients with otitis media because patients with

otitis media may also have respiratory congestion (O'Shea, abstract). One of ordinary skill in the art at the time the invention was made would have been motivated to use the method of McMichael in allergy patients to relieve congestion. Therefore, the combined teachings of McMichael and O'Shea obviate claims 15-20.

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,955,442 or claims 1-7 of U.S. Patent No. 5,726,160 in view of Kuby (1992, Immunology, Kuby, ed., W.H. Freeman and Company, page 360). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of '442 and '160 encompass treating respiratory congestion in a broad genus of patients. The species of treating allergy patients as in claims 1-7 of the instant application is an obvious variant of the claims in '442 and '160. While '442 and '160 do not disclose treating allergy patients, it would have been obvious to use the method of treating respiratory congestion as claimed in '442 or '160 in allergy patients because allergy patients also have respiratory congestion (Kuby, page 360, column 2, first full paragraph). Claims 1-7 encompass numerous routes of delivery while the claims of '442 and '160 are limited to sublingual administration. However, sublingual administration is an obvious species in the claimed invention as in claim 7. The method step of administering DNA in '442 and '160 makes obvious the method step in claims 1-7 in the instant invention. Therefore, the claims of the instant application are obvious in view of the claims in '442 and '160.

12. Claims 8-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,955,442 or claims 1-7 of U.S. Patent No. 5,726,160 in view of Murray (1988, The Textbook of Respiratory Medicine, John F. Murray, ed., W.B. Saunders Company, Philadelphia, page 1038) or over claims 1-7 of U.S. Patent No. 6,100,244. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of '442 and '160 encompass treating respiratory congestion in a broad genus of patients. The species of treating asthma patients as claimed in the instant application is an obvious variant of the claims in '442 or '160. While '442 and '160 do not disclose treating

asthma patients, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of treating respiratory congestion as claimed in '442 or '160 in asthma patients because asthma patients have respiratory congestion (Murray; page 1038, column 2, lines 27-31). Claims 8-14 encompass numerous routes of delivery while the claims of '442 and '160 are limited to sublingual administration. However, sublingual administration is an obvious species in the claimed invention as in claim 14. The method steps of administering the DNA in '442 and '160 make obvious the method step claimed in the instant invention. Therefore, claims 8-14 are rejected under the doctrine of obviousness-type double patenting.

In addition, '244 specifically claims delivering liquid drops of 0.0006 mg DNA in water, saline, albumin or dextrose to asthma patients with shortness of breath while the instant claims encompass delivering DNA to any asthma patient. Therefore, the claims of '244 are an obvious species of claims 8-14 in the instant application.

13. Claims 15-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,955,442 or claims 1-7 of U.S. Patent No. 5,726,160 in view of O'Shea (May 1980, Annals or Otology, Rhinology, and Laryngology, Supp., Vol. 89, pages 285-289) and claims 15-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,948,768. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of '442 and '160 encompass delivering liquid drops of DNA to a broad genus of patients with respiratory congestion. The species of administering DNA to patients with otitis media as claimed in the instant application is an obvious variant of the claims in '442 or '160. While '442 and '160 do not disclose administering the DNA to otitis media patients, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of treating respiratory congestion as claimed in '442 or '160 in asthma patients because otitis media patients may also have respiratory congestion (O'Shea, abstract). Claims 15-19 encompass numerous routes of delivery that are topical while the claims of '442 and '160 are limited to sublingual administration. However, sublingual administration of liquid drops is considered topical because it is on the surface of the tissue under the tongue. Therefore, the method steps of administering the DNA in '442 and '160 make obvious the method step claimed in the instant invention.

The claims of '768 are recite delivering liquid drops of 0.0006 mg of DNA in saline, water, albumin or dextrose to patients with otitis media which is a species of the instant claims. While the instant claims are limited to "topically administering" DNA, sublingual administration is considered topical because it is on the surface of the tissue under the tongue. Therefore, the claims of '768 appear to be obvious variants of claims 15-20 in the instant application.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

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